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IMAGE:



DePuy Synthes Receives 510(k) FDA Clearance for VELYS™ Robotic-Assisted Solution Designed for Use with the ATTUNE® Total Knee System

The VELYS™ Robotic-Assisted Solution is adaptable technology that helps simplify surgeons' existing workflow, and is designed around how surgeons plan, execute and perform surgery for total knee replacement

The VELYS Robotic-Assisted Solution Becomes the Latest Addition to the company's VELYS Digital Surgery Platform

PALM BEACH GARDENS, FL – January 19, 2021 – Today, The Johnson & Johnson Medical Devices Companies* announced that DePuy Synthes** has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the VELYS™ Robotic-Assisted Solution designed for use with the ATTUNE® Total Knee System and its cleared indications for use. It will become part of the broader VELYS Digital Surgery Platform of connected technologies.

With a growing and aging patient population, demand for joint replacement surgery is increasing. But across the industry, data shows up to 20% of knee replacement patients aren't satisfied with the outcome of their surgery.^{1,2} Technology advancements that help surgeons address pain, function and alignment could help facilitate a positive improvement in quality of life for patients.³

The VELYS Robotic-Assisted Solution is a first-of-its-kind table mounted solution, with an efficient design that integrates into any OR. The system adapts to the surgeon's workflow, and is designed to give them the control they are used to and helps them execute accurate bony cuts.⁴ It utilizes advanced planning capabilities, proprietary technology and a next-generation design to help surgeons to accurately resect bones that align and position the implant relative to the soft-tissue during total knee replacement without the need for pre-operative imaging.

It simplifies knee replacement surgery by providing the following benefits:

- Valuable Insights: Gap balance data to help surgeons visualize and predict joint stability
- Versatile Execution: Instinctive, integrated design to give surgeons the control they're used to while optimizing daily OR flow⁵
- Verified Performance: Accurate, consistent plan execution supporting the ATTUNE Total Knee in providing better patient outcomes^{4,7,8,9}

"I've used the VELYS Robotic-Assisted Solution in several of my ATTUNE Knee procedures and have found the VELYS Robotic-Assisted Solution to be accurate, fast and efficient," said Dr. Mark Clatworthy,*** orthopaedic surgeon at MercyAscot Hospital in Auckland, New Zealand, who performed the first ATTUNE Knee procedure using the VELYS Robotic-Assisted Solution. "The device enables me to evaluate the bony anatomy and soft tissue envelope of the knee to plan the optimal implant position and then use the robotic-assisted solution to deliver and execute the plan. I've found my knees to be well balanced at the end of the procedure and my patients are doing well post-operatively."

The VELYS Robotic-Assisted Solution works with the ATTUNE Total Knee, which has been shown to improve patient reported outcomes by working in harmony with the patient's anatomy to deliver both stability and motion through proprietary technologies.^{6,7,8,9,10} Together, these technologies aim to define a high standard for patient performance and elevate the overall knee replacement experience.

"Globally, previous generation robotics have only penetrated key orthopaedic segments between 5-10% of the market. A significant opportunity for combined robotic and digital surgery technology exists. Coupled with the ATTUNE Total Knee, the VELYS Robotic-Assisted Solution is highly differentiated and can help improve clinical outcomes and increase patient satisfaction, providing a more attractive clinical solution to current options on the market." said Aldo Denti, Company Group Chairman, DePuy Synthes Franchise****. "With the addition of the VELYS Robotic Assisted Solution to our VELYS Digital Surgery Platform, we are continuing our vision to be the most personalized and connected orthopaedics company."

The VELYS Digital Surgery platform is comprised of connected technologies that are powered by data insights and designed to elevate the orthopaedic experience for patients, surgeons, and their teams across the entire continuum of care, from pre-operative to post-operative.

The VELYS Robotic-Assisted Solution was designed from proprietary technology developed by Orthotaxy, a privately-held developer of software-enabled surgery technologies acquired by Johnson & Johnson Medical Devices Companies in 2018.

For more information on VELYS™ Digital Surgery visit www.VELYSDigitalSurgery.com.



For more information on the ATTUNE Knee visit www.ATTUNEvidence.com.

About Johnson & Johnson Medical Devices Companies

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people's healthcare experiences. In surgery, orthopaedics, vision and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere.

About DePuy Synthes

DePuy Synthes, part of the Johnson & Johnson Medical Devices Companies, provides one of the most comprehensive orthopaedics portfolios in the world. DePuy Synthes solutions, in specialties including joint reconstruction, trauma, craniomaxillofacial, spinal surgery and sports medicine, are designed to advance patient care while delivering clinical and economic value to health care systems worldwide. For more information, visit www.depuysynthes.com.

** Comprising the surgery, orthopaedics, vision and interventional solutions businesses within Johnson & Johnson's Medical Devices segment.*

*** DePuy Synthes represents the products and services of DePuy Synthes, Inc. and its affiliates.*

**** Dr. Mark Clatworthy is a surgeon innovator for DePuy Synthes Joint Reconstruction.*

***** Aldo Denti is employed by Johnson & Johnson.*

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding VELYS Robotic-Assisted Solution. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of DePuy Synthes and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays, product efficacy or safety concerns resulting in product recalls or regulatory action, changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these

filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Johnson & Johnson Medical Devices Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

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¹ Bourne, R.B, Chesworth, B.M., et al. Patient Satisfaction after Total Knee Arthroplasty: Who is satisfied and who is not? *Clinical Orthopaedics and Related Research*. 2010 468:57-63.

² Baker, P.N., van der Meulen, J.H., et al. The Role of Pain and Function in Determining Patient Satisfaction After Total Knee Replacement. *Journal of Bone & Joint Surgery*. 2007; 89-B:893-900.

³ da Silva RR, Santos AA, de Sampaio Carvalho Junior J, Matos MA. Quality of life after total knee arthroplasty: systematic review. *Rev Bras Ortop*. 2014;49(5):520-7.

⁴ Doan G, Curtis P, Wyss J, Clary C. Resection Accuracy Improved during Robotic-Assisted Total Knee Arthroplasty – a Cadaveric Study. Internal Report 103720852.

⁵ User experience evaluation of the VELYS Robotic-Assisted Solution for total knee (July 2020). Internal Report 103744839.

⁶ Hamilton W, Brenkel I, Barnett S, et al. Comparison of P.F.C. SIGMA to ATTUNE: A Prospective, Multicenter Study. Podium Presentation at the Closed Meeting of the Knee Society, Sept 2018, St Louis, MO, USA. 2018.

⁷ Fisher D, Parkin D. Optimizing the Value of Your Patients' TKA: How to Leverage Data from Patient Reported Outcomes, Becker's Hospital Review, webinar recording, Oct 2019, www.ATTUNEvidence.com/clinical-evidence, last accessed 10-18-19.

⁸ Ranawat CS, White PB, West S, Ranawat AS. Clinical and Radiographic Results of ATTUNE and PFC SIGMA Knee Designs at 2-Year Follow-Up: A Prospective Matched-Pair Analysis. *J Arthroplasty* 2017; 32:431-6.

⁹ Indelli PF, Pipino G, Johnson P, Graceffa A, Marcucci M. Posterior-stabilized total knee arthroplasty: a matched pair analysis of a classic and its evolutionary design. *Arthroplasty Today* 2016; 2:193-8.

¹⁰ Pfitzner T, Moewis P, Stein P, et al. Modifications of femoral component design in multi-radius total knee arthroplasty lead to higher lateral posterior femoro-tibial translation. *Knee Surg Sports Traumatol Arthrosc*. 2017. doi: 10.1007/s00167-017-4622-7. [Epub ahead of print].